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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/656,173

Applicant(s)

WEST ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73,74 and 86-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73,74 and 86-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This application filed September 6, 2000, is a continuation in part of 09/527,026, filed March 16, 2000, which is a continuation in part of 09/520,879, filed April 5, 2000, which claims priority to provisional applications: 60/152,340, filed September 7, 1999; 60/153,233, filed September 13, 1999; 60/155,107, filed September 22, 1999; and 60/179,486, filed February 1, 2000.

Applicants' amendment filed June 28, 2002, paper number 9, has been received and entered. The specification has been amended. Newly submitted drawings (figures 6-10) filed June 28, 2002, replacing figures deleted from the specification have been entered. Non-elected claims 1-72 and 75-86 have been canceled. Claims 73 and 74 have been amended. Claims 87-162 have been added. Claims 73, 74 and 86-162 are pending

Election/Restrictions

Applicant's election without traverse of Group XI, drawn to DNA derived from a human cell, filed June 28, 2002, is acknowledged. Newly added claims 87-162 are drawn to the elected invention. Claims 73, 74 and 86-162 are pending and currently under examination.

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Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specifically, the first line in the application has been amended and the supplemental application data sheet (page 2) indicates benefit to provisional application 60/152,233, filed September 13, 1999, however 60/152,233 was not filed on this date nor does not appear to be not related to the instant application (60/152,233 was filed 09/03/1999, Title of Invention: WINDOWSILL MOISTURE MANAGEMENT SYSTEM). Further, to be a later revised version of 60/152,340 as indicated in the supplemental application data sheet, any subsequent application must have a proceeding application number, which 60/152,233 does not. A review of provisional applications indicates that the intended application number is 60/153,233, filed September 13, 1999.

Appropriate correction is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information

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submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, pages 49-51 provide a numbered list of references, and cited references are provided throughout the specification, however none of references are provided or listed in an IDS. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: on page 36, lines 5 and 18, the specification recites "(flow fish)" and "(flow FISH, ref 32)", respectively. It is unclear to what this in reference.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall

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introduce new matter into the disclosure of an application after the filing date of the application".

Specifically, the limitation in independent claims reciting "comprising tandem repeat sequences that are more uniform than those present in telomeres of cells" of said non-human mammal is considered new matter. A review of the instant specification noted by Applicants (page 12, lines 3-9) provides literal support for 'uniform tracts of telomeric repeats', however there is no support for the comparison to other cells or cell types, nor any specific characterization of the length or for the location of the more uniform repeats in the chromosome. Review of the working examples indicates that telomerase activity was measured, and the length of the telomeres was measured by flow cytometry (page 36), however there was no specific characterization of the 'uniformity' of the telomeres.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 73, 74 and 86-162 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly

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conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claim 73, 93, 102, 110, 125, 128, 131, 147 are unclear and confusing in the recitation of "are more uniform than those present in telomeres of cells of said non-human mammal" because the antecedent basis for the comparison is between the same mammal. It is unclear how the two same non-human mammals can have different properties. Further, the metes and bounds are unclear because the comparison of one DNA to another is subject the source of DNA chosen, and thus can vary depending on what is being compared. Additionally, it is unclear what the term

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‘more uniform’ encompasses because what is being measured/compared is not specifically set forth in the claims nor the specification. Finally, the recitation of ‘DNA from a cell’ is unclear to whether the DNA is present in a cell, or must be isolated from a cell, or can be provided by any other means or source. The specific nature and context of the DNA being claimed is unclear. From the context of the claim, it is clear that the DNA being claimed can vary, in particular with respect to the telomere. Further, dependent claims recited and indicate that the DNA can be modified (see claim 91 for example). The metes and bounds of the DNA being claimed is indefinite because other elements or characteristics encompassed by the claim are not clearly set forth.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 73, 74, 87-92, 102-109, 119-124 and 147-162 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to “DNA of a cell” (see claim 73), a ‘chromosome’ (see claim 119 and 161) and a ‘cell nucleus’ (see claim 162), however the claims do not provide a specific context for said claimed DNA. chromosome or nucleus. A review of the specification indicates that the “DNA” is produced in a

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cell and that the cell can be present in the context of a non-human mammal. Moreover, the specification teaches that the DNA containing telomeres is produced in the context of chromosomal DNA. Therefore, because the context of the claimed DNA is not specifically defined in the claim, and can fairly be interpreted to be in the context of a non-human mammal, the claim reads on any non-human mammal present in nature.

Amending the claim to encompass an isolated DNA would obviate the basis of the rejection.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to generally a DNA, a chromosome or a nucleus in which the telomere is of a more uniform tandem repeat and of a particular length. The specification teaches that practice of nuclear transfer methodology with cows results in a cell in which the telomeres of said NT cell and the resulting animal are greater in length than would be expected from experiments performed in sheep (for example pages 2-4). Review of the specification teaches that nuclear transfer methodology results in an NT unit that can be implanted into an appropriate host and grown to a viable offspring. More specifically, using nuclear transfer methodology to produce cows results in the cell of the offspring having chromosomes with telomeres of similar length representative of cows of similar age not produced by artificial means. However, review of the specification does not provide any specific guidance for the use of the DNA, chromosome

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or nucleus comprising DNA with said telomeres. As indicated above, it would not be contested that practicing the method of nuclear transfer results in such a telomere, but the specification does not teach what use such DNA has. The claimed DNA is not supported by a specific asserted utility because the disclosed use of the nucleic acid is not even discussed in the instant specification, or readily apparent from the art of record. While the nuclear transfer methods result in an NT cell and cells of an offspring generated from said NT cell in which the telomere has increased length the use of such material is not disclosed. As proposed in the specification, it may be that greater telomere length may bestow beneficial characteristics to the animal or cell resulting from nuclear transfer, however this does not provide any guidance for the use of the DNA itself. Further, these characteristics are represent benefits to a cell and not the DNA itself. Moreover, the benefits to the cell require the entire intact nuclear chromosomal material more than greater telomere length alone as set forth in the claims. In this case, the specification provides no asserted nor intended use for the claimed DNA. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the DNA such that another non-asserted utility would be well established for the claimed product.

Claims 73, 74 and 86-162 are also rejected under 35 U.S.C. 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed inventions.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Stice *et al.* (US Patent 5,945,577-issue date August 31, 1999).

Stice *et al.* teach a method of improved cloning of non-human mammals comprising the use of nuclear transfer methodology. Using donor cells from pigs and cattle the methods were reduced to practice (see example 1). As indicated in the allowed claims the methods can be used to clone a non-human mammal (claim 1 for example), and includes the production of off-spring that would contain every cell within said cloned animal (claim 7). Further, it is taught the methodology can be used to generate transgenic animals wherein heterologous nucleic acid sequences can be introduced. Because the methods taught by Stice *et al.* are the same as used in the instant specification the cells produced by the methods would be the same. In particular, carrying out the methods of nuclear transfer taught by Stice *et al.* would produce cells in which the telomeres are affected as described in the instant application. It is noted that Stice *et al.* do not specifically characterize the telomeres in the cells or animals produced, however since nuclear transfer methodology is used, the resulting cell(s) would inherently have affected

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telomeres. Review of specific teachings of the instant specification does not provide any specific alternative steps not generally known in the art for nuclear transfer methodology.

Therefore, the teaching and practice of nuclear transfer methodology in the prior art would result in a cell containing DNA as instantly claimed. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Stice *et al.* teach that CICM cells produced by nuclear transfer can be used as nuclear donors (column 15, lines 44-47). The DNA used in this methodology is the chromosome present in the nucleus of a cell, therefore Stice *et al.* teach DNA that anticipates the claims.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Cibelli *et al.* (Science 280:1256-1258, May 1998).

Cibelli *et al.* teach a method of calves comprising the use of nuclear transfer methodology. Using the nuclear material from fetal fibroblast cells several cloned calves were

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produced (see figure 2). Because the methods taught by Cibelli *et al.* are the same as used in the instant specification the cells produced by the methods would be the same. In particular, carrying out the methods of nuclear transfer taught by Cibelli *et al.* would produce cells in which the telomeres are affected as described in the instant application. As discussed above for Stice *et al.* it is noted that Cibelli *et al.* do not specifically characterize the telomeres in the cells or animals produced, however since nuclear transfer methodology is used, the resulting cell(s) would inherently have affected telomeres. Therefore, the teaching and practice of nuclear transfer methodology in the prior art would result in a cell containing DNA as instantly claimed. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Cibelli *et al.* teach the isolation of genomic DNA for PCR and Southern blot analysis (see figures 3 and 4). The DNA analyzed by Cibelli *et al.* anticipates the claimed DNA products.

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Conclusion

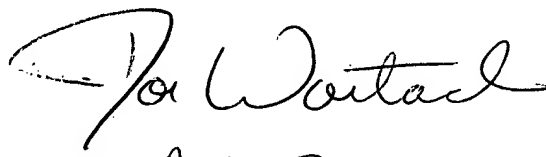
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach



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